K022513

510(k) SUMMARY

OCT 25 2002

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-0818 Fax
Contact:	Florence A. Caikoski Regulatory Affairs Associate
Date Prepared:	July 9, 2001

B. Trade Name: Medcomp Vascu-Sheath® Introducer Set
Common Name: Introducer, Catheter
Classification: DYB
C.F.R. Section: 870.1340

C. Predicate Device: K993191 TFX Medical Introducer Assembly

D. Device Description:

The Medcomp Vascu-Sheath® Introducer Set is a single use device used to obtain vascular access and facilitate catheter insertion. The Medcomp Vascu-Sheath® Introducer Set consists of an introducer sheath and vessel dilator.

E. Intended Use:

The Medcomp Vascu-Sheath® Introducer Sets are indicated for use in obtaining central venous access to facilitate catheter insertion or placing pacing leads into the central venous system.

F. Comparison to Predicate Device:

The technological characteristics of the Vascu-Sheath® Introducer Set are substantially equivalent to the predicate device in terms of intended use, design, material type, performance, and method of sterilization.

G. Performance Data:

In Vitro performance data for the Medcomp Vascu-Sheath® Introducer Set, including peel force, demonstrates that this device is substantially equivalent to the legally marketed device.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2002

MEDCOMP®
Ms. Florence A. Caikoski
Regulatory Affairs Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K022513
Medcomp Vascu-Sheath® Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: 74 DYB
Dated: July 29, 2002
Received: July 30, 2002

Dear Ms. Caikoski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K022513

Device Name: MEDCOMP Vascu-Sheath® INTRODUCER SET

Indications for use:

THE MEDCOMP Vascu-Sheath® INTRODUCER SETS ARE INDICATED FOR USE IN OBTAINING CENTRAL VENOUS ACCESS TO FACILITATE CATHETER INSERTION OR PLACING PACING LEADS INTO THE CENTRAL VENOUS SYSTEM.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022513